

Notice of Allowability

Application No.

10/049,608

Applicant(s)

GELBER, COHAHA

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 20 December 2005.
2. ☒ The allowed claim(s) is/are 65-78.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

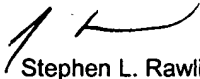
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>20070111</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |


Stephen L. Rawlings, Ph.D.
Primary Examiner
Art Unit 1643

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with Melissa B. Wenk on January 25, 2007.
3. The application has been amended as follows:

In the claims:

Claims 1-64. (Canceled)

Claim 65. (Currently Amended) A method for detecting ovarian cancer in a patient comprising:

a) obtaining a biological sample from the patient;
b) contacting the biological sample with a monoclonal antibody which is produced by a hybridoma cell line deposited at the American Type Culture Collection (ATCC®) as ATCC Accession Number PTA-450 or an antigen binding fragment thereof; and

c) detecting the complex formed by the monoclonal antibody ~~bound to its~~ and the antigen to which the antibody binds,

wherein the detection of the complex in the biological sample in an amount greater than an amount of the complex in a normal biological sample indicates the presence of ovarian cancer.

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Claim 66. (Previously Presented) The method of claim 65 wherein the sample is contacted with the antigen binding fragment of the monoclonal antibody which is produced by a hybridoma cell line deposited at the American Type Culture Collection (ATCC®) as ATCC Accession Number PTA-450.

Claim 67. (Previously Presented) The method of claim 66 wherein the antigen binding fragment is an F(ab')₂, Fab', Fv, Fd', or Fd.

Claim 68. (Currently Amended) The method of claim 65 further comprising labeling the monoclonal antibody or antigen binding fragment thereof with a detectable moiety.

Claim 69. (Previously Presented) The method of claim 68 wherein the detectable moiety is a fluorophore, a chromophore, a radionuclide, or an enzyme.

Claim 70. (Previously Presented) The method of claim 65 wherein the biological sample is body fluid or tissue.

Claim 71. (Currently Amended) A method for detecting ovarian cancer in a patient comprising:

- a) obtaining a biological sample from the patient;
- b) measuring in the biological sample a level of an antigen that ~~is capable of binding~~ binds to a monoclonal antibody which is produced by a hybridoma cell line deposited at the American Type Culture Collection (ATCC®) as ATCC Accession Number PTA-450 or an antigen binding fragment thereof, wherein the antigen
 - (i) is a single polypeptide with a molecular weight of about 76 kDa to about 213 kDa as determined by SDS PAGE under reducing conditions;
 - (ii) is absent from human peripheral blood mononuclear cells, human B cells, and human B cell myelogenic leukemia cells; and
 - (iii) is glycosylated,

wherein the detection of the antigen in the biological sample in an amount greater than an amount of the antigen in a normal biological sample indicates the presence of ovarian cancer.

Claim 72. (Currently Amended) The method of claim 71 wherein the antigen is detected by contacting the antigen with a monoclonal antibody which is produced by a hybridoma cell line deposited at the American Type Culture Collection (ATCC®) as ATCC Accession Number PTA-450 or an antigen binding fragment thereof.

Claim 73. (Previously Presented) The method of claim 72 wherein the antigen binding fragment is an F(ab')₂, Fab', Fv, Fd', or Fd.

Claim 74. (Currently Amended) The method of claim ~~[[71]]~~ 72 further comprising labeling the monoclonal antibody or antigen binding fragment thereof with a detectable moiety.

Claim 75. (Previously Presented) The method of claim 74 wherein the detectable moiety is a fluorophore, a chromophore, a radionuclide, or an enzyme.

Claim 76. (Previously Presented) The method of claim 71 wherein the biological sample is body fluid or tissue.

Claim 77. (Previously Presented) The method of claim 70 wherein the body fluid is blood, serum, or plasma.

Claim 78. (Previously Presented) The method of claim 76 wherein the body fluid is blood, serum, or plasma.

Examiner's Statement of Reasons for Allowance

4. The following is an examiner's statement of reasons for allowance:

Applicant's amendments filed December 20, 2006, have obviated the grounds of rejection set forth in the preceding Office action mailed July 18, 2006, and the prior art does not teach or fairly suggest detecting ovarian cancer in a patient by a process comprising detecting in a biological sample from the patient the presence of the antigen to which the monoclonal antibody produced by the deposited hybridoma binds.

Furthermore, Applicant has made the necessary assurances in satisfaction of the deposit requirement.

Notably, Applicant has not pointed out in the amendment filed December 20, 2006, specifically where in the specification, as originally filed, written support for the present claims is found; nonetheless, proper support for the language of the claims has been found in the specification at, e.g., the original claims; page 11, line 19, through page 12, line 30; page 25, lines 26-29; page 27, line 15, through page 28, line 24; page 33, lines 1-11; and page 36, line 6, through page 44, line 14.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

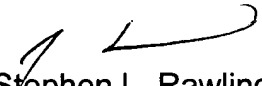
6. Claims 65-78 are allowed.
7. Claims 65-78 have been renumbered as claims 1-14, respectively.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is

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(571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Stephen L. Rawlings, Ph.D.
Primary Examiner
Art Unit 1643

slr
January 25, 2007